A prospective, multi-center, post market randomized controlled trial comparing VT ablation outcomes using remote MAGNETIC navigation guided substrate mapping and ablation versus manual approach in a low LVEF population

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To demonstrate that ventricular tachycardia (VT) ablation using the Niobe* ES system results in superior outcomes compared to a manual approach in subjects with ischemic scar VT in a low ejection fraction population.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON43344

Source
ToetsingOnline

Brief title
The MAGNETIC-VT Study

Condition

- Cardiac arrhythmias

Synonym
cardiac arrythmia, ventricular tachycardia

Research involving

Human

Sponsors and support

Primary sponsor: Stereotaxis
Source(s) of monetary or material Support: Stereotaxis,Stereotaxis (zie C17)

Intervention

Keyword: Ablation, Cardiac Arrhythmias, Ventricular Tachycardia (VT)

Outcome measures

Primary outcome

1. Freedom from any recurrence of VT through 12 months.

Secondary outcome

2. Acute Success: Defined as non-inducibility of clinical VT and/or other monomorphic VT, using typical stimulation protocol for induction, up to 3 extra-stimuli brought in to ventricular refractoriness at 2 drive cycle lengths, in two sites).

3. Freedom from any VT at 1 year in a large scar subpopulation (defined as patients with a scar total surface area > the median scar total surface area for the total population as determined by electroanatomic mapping).

4. Procedure related major adverse events defined as death, cardiac tamponade, stroke, and bleeding requiring surgical intervention through 48 hours post-procedure, and progressive heart failure related to VT/VF recurrence within 48 hours post-ablation.

5. Mortality rate through 12-months follow-up

Study description

Background summary

Ischemic cardiomyopathy (ICM) is a prevalent cardiac disease around the world. ICM patients with history of myocardial infarction consist of a significant population referred for ventricular tachycardia (VT) RF ablation. Catheter ablation of VT is effective with recurrent sustained VT episodes and particular useful in the patients with implanted defibrillators.
In contrast to conventional manual approach, magnetic navigation system (MNS) offers remote guidance of ablation catheters during ablation for cardiac arrhythmias, by navigating the magnetic-tipped catheter precisely to the substrate targets. Recently, Bhaskaran et al (2015) reported that the latest MNS platform, Niobe ES, could produce larger lesion dimensions compared to manual approach in the presence of simulated wall motion in a bench-top model, consistent with greater catheter stability. MNS has provided important clinical advantages in safety due to the remote magnetic vector control, atraumatic catheter design and less physical stress and radiation exposure for the operator.
Numerous studies have revealed significant advantages, mainly for the ablation of Non-Structural Heart Disease VT (NSHDVT) when compared to conventional methods. A single center study with consecutive case series (2015) demonstrated a better long-term outcome of MNS in a heterogeneous VT (ischemic mixed with non-ischemic) cohort by the intention-to-treat analysis. Its better long term outcome, more than 2 years, for the MNS group is likely linked to the higher acute success rate. A possible explanation for the higher acute success in MNS guided VT ablation is enhanced maneuverability and improved catheter stability using the latest platform. However, despite these impactful reports in MNS guided VT ablations, the superior outcome evidence in ischemic VT in MNS is lacking from randomized study design prospective. It remains a major debate in the VT ablation field.

Study objective

To demonstrate that ventricular tachycardia (VT) ablation using the Niobe* ES system results in superior outcomes compared to a manual approach in subjects with ischemic scar VT in a low ejection fraction population.

Study design

This study is a randomized, single-blind, prospective, multi-center post market study. Patients will be enrolled and randomized 1:1. A total of 386 subjects (193 per treatment group) will be randomized 1:1 between treatment with the Niobe ES system and treatment via a manual procedure. Patients are to be followed through 12-month follow-up (visits at 3 [remote visit allowed], 6, 9

[remote visit allowed] and 12 months).

Intervention

The ablation of ventricular arrhythmias is a standard treatment in specialized hospitals. In this trial the patients will be randomized between two ablation techniques; the conventional manual approach and the approach where the ablation occurs by means of magnetical navigation where the catheters are guided through magnets (MN, Magnet Navigation). MN exists for years already and the Erasmus MC was one of the first centers to apply this technique. Over time this technique has improved, amongst others the ability to guide the catheters.

Study burden and risks

In essence the burden for the patient will not differ between the two techniques. Prior to an ablation it is difficult to establish what the exact time burden for the patient will be. The biggest risks for an ablation are amongst others: thromboembolic complications, perforation and tamponade, bleedings. In this research there are no other complication expected than compared to the standard.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Patient is 18 years of age or older;
2. Patient has provided written informed consent;
3. Patient has an implantable cardioverter defibrillator (ICD) previously implanted;
4. Drug refractory monomorphic VT;
5. Patient is a candidate for ischemic VT RF ablation;
6. Patient has had a myocardial infarction;
7. LVEF * 35%.

Exclusion criteria

1. Non-ischemic VT;
2. History of stroke within 1 month prior to enrollment;
3. Acute MI within 30 days prior to enrollment;
4. Unstable angina;
5. Cardiac surgery within 60 days prior to enrollment;
6. Patient is pregnant or nursing;
7. Limited life expectancy of 1 year or less (Subjects requiring LVAD/IABP intraprocedural support may be enrolled as long as life expectancy is at least 1 year following the ablation procedure.)
8. Patient is unable or unwilling to cooperate with the study procedures;
9.. Known presence of intracardiac thrombi determined by echocardiography;
10. Major contraindication to anticoagulation therapy or coagulation disorder;
11. Previous pericarditis or cardiac tumor;
12. Previous thoracic radiation therapy;
13. Any other reason the investigator considers the subject ineligible.

Study design

Design

Study phase: 4

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-08-2016
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	The Niobe ES system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-07-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-11-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL57060.078.16